

Message Text

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PAGE 01 STATE 005220
ORIGIN HEW-06

INFO OCT-01 AF-08 ARA-10 EUR-12 EA-09 NEA-10 ISO-00 OES-06
SIG-02 EB-07 COME-00 /071 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/OIH: BROYSTER
ARA/EX:CJACOBINI(INFO)
NEA/EX:EGABINGTON(INFO)
EA/EX:JRCUNNINGHAM(INFO)
EUR/EX:JLTULL(INFO)
AF/EX:JTIERNEY(INFO)

-----110449Z 000031 /15

P 102250Z JAN 77

FM SECSTATE WASHDC

TO AMEMBASSY MEXICO PRIORITY

AMEMBASSY TOKYO PRIORITY

AMEMBASSY PARIS PRIORITY

AMEMBASSY STOCKHOLM PRIORITY

AMEMBASSY CANBERRA PRIORITY

AMEMBASSY WELLINGTON PRIORITY

AMEMBASSY PRETORIA PRIORITY

AMEMBASSY MADRID PRIORITY

AMEMBASSY CARACAS PRIORITY

AMEMBASSY QUITO PRIORITY

AMEMBASSY LIMA PRIORITY

AMEMBASSY SAN SALVADOR PRIORITY

AMEMBASSY SAN JOSE PRIORITY

AMEMBASSY MANILA PRIORITY

AMEMBASSY BRUSSELS PRIORITY

AMEMBASSY LAGOS PRIORITY

AMEMBASSY ROME PRIORITY

AMEMBASSY LISBON PRIORITY

AMEMBASSY LONDON PRIORITY

AMCONSUL HONG KONG PRIORITY

AMEMBASSY SINGAPORE PRIORITY

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AMEMBASSY BERN PRIORITY
AMEMBASSY AMMAN PRIORITY
AMEMBASSY KUWAIT PRIORITY
AMCONSUL CURACAO PRIORITY
AMEMBASSY BANGKOK PRIORITY
AMEMBASSY ABU DHABI PRIORITY
AMEMBASSY PARAMARIBO PRIORITY

AMEMBASSY BRIDGETOWN PRIORITY
AMEMBASSY GEORGETOWN PRIORITY
AMEMBASSY TEL AVIV PRIORITY
AMEMBASSY JAKARTA PRIORITY
AMEMBASSY COLOMBO PRIORITY
AMEMBASSY ATHENS PRIORITY
AMEMBASSY HELSINKI PRIORITY
AMEMBASSY PORT OF SPAIN PRIORITY
AMEMBASSY LUSAKA PRIORITY
AMEMBASSY SEOUL PRIORITY

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.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, XX

SUBJECT: EXCESSIVE MOISTURE INVITRO DIAGNOSTIC PRO-
DUCT (RECALL NO. T-002-7)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: HUMAN PLASMA FOR INVITRO DIAGNOSTIC
USE. PRODUCT PACKAGED IN LYOPHILIZED 1ML. SIZE VIALS.
THE VIALS ARE PACKAGED IN UNITS OF TEN'S. THE PRODUCT
IS USED AS A NORMAL CONTROL IN COAGULATION TESTS.

PRODUCT IDENTIFICATION: "ORTHO PLASMA COAGULATION CON-
TROL", ORTHO DIAGNOSTICS INC., RARITAN, NEW JERSEY 08869.
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THE PRODUCT IS IDENTIFIED WITH CATALOG NO. 3138. ALL
LOTS EACH BEARING A SEQUENTIAL LOT NO. 11M50 THROUGH
5P91 ARE UNDER RECALL.

MANUFACTURER: ORTHO DIAGNOSTICS INC., ARLINGTON, TEXAS.

RECALLING FIRM: ORTHO DIAGNOSTICS INC., RARITAN, N.J.
08869.

2. REASON FOR RECALL:

RETESTING OF ALL PRODUCTS IN LYOPHILIZER ROOMS NO. 1 AND 2
THE ARLINGTON, TEXAS PLANT SHOWED THAT 9 OF 43 LOTS
EXCEEDED THE FIRMS MOISTURE SPECIFICATIONS. THE EXCESS
MOISTURE MAY AFFECT THE CLOTTING TIME.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES
TO DETERMINE IF THEY HAVE RECEIVED RECALL LETTER DATED
27 SEPTEMBER 1976. ALL CONSIGNEES ARE TO CONTACT THE

FIRM'S CUSTOMER SERVICE DEPARTMENT FOR RETURN AUTHORIZATION. THE FIRM'S RECALL CONTACT IS DANIEL T. MC KIETHAN, JR. - TELEPHONE 201-542-2406.

4. CONSIGNEES AS FOLLOWS:

MEXICO
JOHNSON AND JOHNSON DE MEXICO SA DE CV
APARTADO POSTAL 1133
MEXICO 1, D.F. MEXICO

JAPAN
SANKO JUNYAKU
10-6 IWAMOT O-CHO
1 CHOME CHIYODA-KUTMM BLDG.
TOKYO, 101 JAPAN

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FRANCE
LE BRUN LABORATORIES
5 RUE DE LUBECK 75
PARIS 16E, FRANCE

SWEDEN
CILAG CHEMIE A B
FACK S191-07 SOLLENTUNA
SWEDEN

AUSTRALIA
ETHNOR PTY LTD
P O BOX 134
NORTH RYDE N S W 2113
AUSTRALIA

NEW ZEALAND
ETHNOR PTY LTD
27 CROWHURST ST
NEW MARKET
AUCKLAND, NEW ZEALAND

SOUTH AFRICA
ETHNOR LABORATORIES PTY LTD
P O BOX 273
HALFWAY HOUSE 1685
TRANSVAAL, SOUTH AFRICA

SPAIN

JOHNSON AND JOHNSON S A
GUSTAVO FERNANDEZ BALBUENA 2
MADRID 2, SPAIN

VENEZUELA
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JOHNSON AND JOHNSON DE VENEZUELA SA
APARTADO 60349
CARACAS 106, VENEZUELA

ECUADOR
JOHNSON AND JOHNSON HEMISPHERICA SA
P O BOX 7206
GUAYAQUIL, ECUADOR

PERU
JOHNSON AND JOHNSON PERU FOR:
RICHARD O CUSTER SA
CASILLA 68L
LIMA, PERU

EL SALVADOR
JOHNSON AND JOHNSON GUATEMALA FOR:
GOBIERNO DE ELSALVADOR
HOSPITAL FRANCISCO MENENDEZ
AHUACHAPAN, EL SALVADOR, CA

COSTA RICA
JOHNSON AND JOHNSON GUATEMALA FOR:
CENTRAL DISTRIBUIDORA
INDUSTRIAL SA
AVE 5 CALLE 6
EDIFICIO LOS LEONES
SAN JOSE, COSTA RICA

PHILIPPINES
JOHNSON AND JOHNSON PHILIPPINES INC.
P O BOX 811
MAKATI RIZAL
D-708, PHILIPPINES

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BELGIUM
ORTHO PHARMACEUTICA NV
ANTWERPSEWEG 19-21
2340 BEERSE, BELGIUM

NIGERIA
JOHNSON AND JOHNSON NIGERIA LTD
P O BOX 3136
LAGOS, NIGERIA

ITALY
CILAG CHIMIE ITALIANA SPA
CASELLA POSTAL 4387
20100 MILANO, ITALY

PORTUGAL
JOHNSON AND JOHNSON LIMITADA
APARTADO 17
QUELUZ, PORTUGAL

ENGLAND
ORTHO PHARMACEUTICAL LIMITED
P O BOX 79
SAUNDERTON, HIGH WYCOMBE
BUCKINGHAMSHIRE HP144HJ
ENGLAND

HONG KONG
JOHNSON AND JOHNSON(HONG KONG) LTD
P O BOX 979
HONG KONG

SINGAPORE
JOHNSON AND JOHNSON PTE LTD
P O LOCKED BAG SERVICE NO.6
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JURONG TOWN, SINGAPORE 22

SWITZERLAND
CILAG CHIMIE AG
HOCHSTRASSE 205-209
8201 SCHAFFHAUSEN
SWITZERLAND

JORDAN
JORDAN UNIVERSITY HOSPITAL
P O BOX 9174
AMMAN, JORDAN

ARABIAN GULF GUYANA
TAREQ COMPANY DAVSONS LTD
P O BOX SAFAT 20506 P O BOX 272
KUWAIT, ARABIAN GULF GEORGETOWN, GUYANA

NETHERLANDS ANTILLES ISRAEL
ST. ELIZABETH HOSPITAL CHEMICALS AND TECHNICALS
BREEDSTRAAT 193(0) SUPPLIES LTD
WILLEMSTAD P O BOX 10
CURACAO, NETHERLANDS ANTILLES TEL-AVIV, ISRAEL

THAILAND INDONESIA
NEW FRENCH DISPENSARY PT JANJI UTAMA
693-699 SIPHYA ROAD ETHICAL PRODUCTS DEPT
BANGKOK, THAILAND TROMOLPOS, INDONESIA

ARABIAN GULF U S GOVERNMENT
GOVERNMENT OF ABU DHABI DEFENSE PERSONNEL SUPPORT
DIRECTOR OF DEPT OF HEALTH CENTER
P O BOX 233 DEFENSE SUPPLY AGENCY
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ABU DHABI, ARABIAN GULF 2800 SOUTH 20TH STREET
PHILADELPHIA, PA 19101
SURINAM (APO NY FOR AUGSBURG,
C KERSTEN AND CO NV GERMANY)
P O BOX 1808
PARAMARIBO, SURINAM SRI LANKA
CROWN AGENTS
NETHERLANDS ANTILLES 3100 MASSACHUSETTS AVE,NW
LABORATORIUM VOOR DE WASHINGTON, D.C. 20008
VOLKSGEZONDHEID FOR: DEPT OF GOVERNMENT
ARUBA, NETHERLANDS ANTILLES SUPPLY

COLOMBO, SRI LANKA
BARBADOS (WEST INDIES)
W.B. HUTCHINSON AND CO LTD PUERTO RICO
CAVANS LANE US GOV'T SUPPLY OFFICER
BRIDGETOWN, BARBADOS (W INDIES) US NAVAL STATION BOX 2
FPO NEW YORK 09551 FOR:
UNICEF PUERTO RICO
UNITED NATIONS PROCESSING
UNIT, NY, NY, 10017 FOR GREECE
UNICEF CHRISTOPHER PALLIDES
C/O MR. A.A. ELARIGI 15 ALEXANDER SOUTSOU ST
LIAISON OFFICER ATHENS T-134, GREECE
P O BOX 551

SANA'A, YEMEN ARAB REPUBLIC

FINLAND

MR. BROR FELIXSON

THE FINNISH FAIR CORP

P O BOX 24

SF 00521 HELSINKI 52, FINLAND

NETHERLANDS ANTILLES

B A LEON LTD

P O BOX 122

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CURACAO, NETHERLANDS ANTILLES

TRINIDAD

MINISTRY OF HEALTH

GOVERNMENT OF TRINIDAD AND TOBAGO

PORT OF SPAIN, TRINIDAD

ZAMBIA

NATIONAL DRUG COMPANY

P O BOX 202

KABWE, ZAMBIA

KOREA

PRESBYTERIAN MEDICAL CENTER

JEONJU, KOREA 520

ATTN: MR. MERRIT H GRUBBS

KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, BLOOD, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 10-Jan-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE005220
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770009-1052
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770165/aaaacfeg.tel
Line Count: 366
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 07e9b6db-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 7
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 15-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3630468
Secure: OPEN
Status: NATIVE
Subject: EXCESSIVE MOISTURE INVITRO DIAGNOSTIC PRO- DUCT (RECALL NO. T-002-7)
TAGS: OGEN, ETRD, TBIO, XX
To: MEXICO TOKYO MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/07e9b6db-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009